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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,473	07/27/2006	David Harold Drewry	PR60714USW	1716

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GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B482
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

NOTIFICATION DATE	DELIVERY MODE
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06/15/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
LAURA.M.MCCULLEN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

Office Action Summary	Application No.	Applicant(s)	
	10/597,473	DREWRY ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,9 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,9 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060727</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-5, 8-9 and 14 are pending in this application.

Election/Restrictions

Applicant's election of Group I, claims 1-5, 8-9 and 14 drawn to compounds of formula (I) wherein X is pyrimidinyl group, in the reply filed on March 26, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

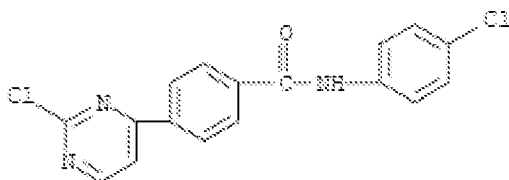
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

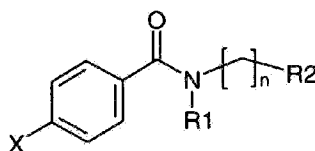
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-2, 4, 8 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al., WO 2006/047516 (effective filing date: October 26, 2004). The instant claims read on reference disclosed compound, see the intermediate compound in Example 352, page 120 (structure depicted below for convenience):

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Note: Applicant's claim for priority benefit over U.S. Provisional Application No. 60/540,621 filed January 30, 2004 is acknowledged. Applicant can not, however, rely on the priority benefit to overcome the above rejection because the prior application does not support the instant claims. See, for example, the prior application discloses:

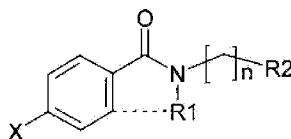


(I)

wherein:

- R1 is hydrogen or C₁₋₆alkyl;
- n is 1, 2, 3 or 4;

as compared to the instant claim 1 wherein it is recited:



(II)

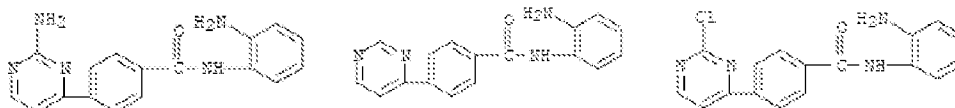
wherein:

- R1 is hydrogen or C₁₋₆alkyl or as indicated by the dotted line is fused to the phenyl forming a 5 or 6 membered ring, optionally containing a double bond;
- n is 0, 1, 2, 3 or 4;

As can be seen from the above, the prior application does not disclose all of the limitations of the instant claims and therefore, the instant claims are not entitled to the priority benefit of S.No. 60/540,621 filed January 30, 2004.

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2. Claims 1-2, 8 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Stokes et al., WO 2003/087057. The instant claims read on reference disclosed compounds, see the compounds of formula (I) and the corresponding species of the Examples, particularly compounds 9-11 in Table 1 (page 31). (Structures depicted below for convenience):



Claim Rejections - 35 USC § 103

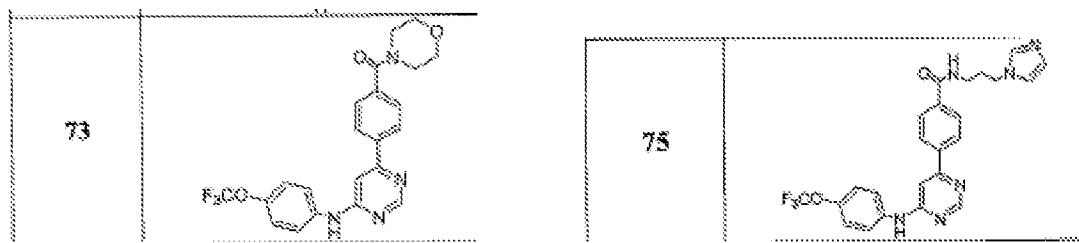
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

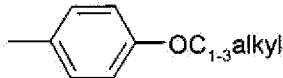
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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1. Claims 1-5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al., WO 2004/089286 (International filing date: April 2, 2004 and effective filing date: April 4, 2003). The reference teaches a generic group of pyrimidine compounds, which embraces applicant's instantly claimed compounds. See formula I in page 2, wherein one X^1 and X^2 is =N-; L is a bond; R^3 is C_6 aryl- C_0 alkyl; R^1 is $-X^3NR^6R^7$ wherein X^3 is a bond, R^6 is hydrogen or alkyl, and R^7 is aryl optionally substituted with halo, alkyl, haloalkyl, alkoxy, haloalkoxy, etc. Further, see the compounds of the Examples including those in the Tables, particularly, the compounds 58 (page 34); 63, 65 (page 35); 73, 75 (page 36); 90 (page 38); 103 (page 40); etc. The compounds are taught to be useful as pharmaceutical agents, see pages 18-20. The instant claims differ from the reference by reciting a more limited subgenus than the reference. For example, see the reference compound 75 (depicted below for convenience):



The above compound contains a 4-trifluoromethoxy-phenyl- attached to the amino nitrogen. The

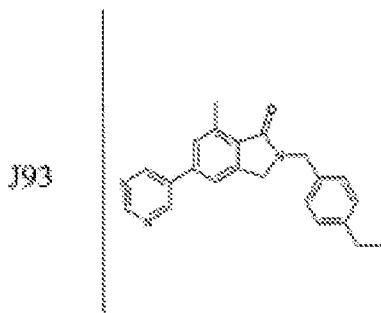
instant claims recite that when Y_1 or Y_2 is NR^5R^6 , R^5 or R^6 can be . The reference, however, teaches the equivalency of haloalkoxy and haloalkyl groups as these are disclosed to be alternative substituents on the phenyl ring. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar

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properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents.

One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

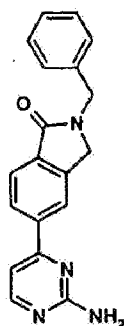
2. Claims 1, 3, 8, 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clayton et al., WO 2006/020879 (effective filing date: August 13, 2004). The reference teaches a generic group of isoindoline compounds, which embraces applicant's instantly claimed compounds. See formula (I) in page 2, wherein R⁵ is an optionally substituted six membered ring containing two nitrogen atoms, e.g., pyrimidine; R⁴, R⁶ and R⁷ are H, alkyl, etc.; R¹ is an optionally substituted 3- to 7-membered ring; and see the corresponding species, for example compound K41 (page 106) and J93 (page 137). The compounds are taught to be useful as pharmaceutical agents, see the abstract. The instant claims differ from the reference by reciting specific species a subgenus of the reference genus. For example, see the reference compound 75 (depicted below for convenience):



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The above compound contains a pyrimidin-5-yl group attached to the isoindoline as compared to the instant claims which recite a pyrimidin-4-yl group. The reference, however, teaches the equivalency of the 4- and 5-positions of the pyrimidinyl groups as these are taught to be alternative substituents for the isoindoline core. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

Alternatively, the compounds of the instant claims are positional isomers of reference compounds. See for example, a compound of claim 9 which is: 5-(2-amino-4-pyrimidinyl)-2-(phenylmethyl)-2,3-dihydro-1H-isoindol-1-one (structure depicted below for convenience):



The reference teaches that the cyclic groups of the substituents attached to the isoindoline (i.e., pyrimidine and phenyl) may be optionally substituted. The compounds of the instant claims (see

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for example, the compound of claim 9 depicted above) differ from the reference compounds by having a pyrimidin-4-yl group as compared to pyrimidin-5-yl group for the reference disclosed compound and therefore, the instantly claimed compounds are positional isomers of the reference compounds. It would have been obvious to one having ordinary skill in the art at the time of the invention to prepare the instantly claimed compounds because they are positional isomers of the reference compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such isomeric compounds are suggestive of one another and would be expected to share similar properties and therefore, the same use as taught for the reference compounds, i.e., as pharmaceutical agents. It has been held that a compound, which is structurally isomeric with a compound of prior art is prima facie obvious absent unexpected results. *In re Finley*, 81 USPQ 383 (CCPA 1949); *In re Norris*, 84 USPQ 458 (CCPA 1950); *In re Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904 (Fed. Cir. 1990).

Note: Applicant can not rely on the priority benefit based on U.S. Provisional Application No. 60/540,621 filed January 30, 2004 to overcome the above rejections because the prior application does not support the instant claims. (See the explanation above under 35 USC 102 rejection).

Receipt is acknowledged of the Information Disclosure Statement filed on July 27, 2006 and a copy is enclosed herewith.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Deepak Rao/
Primary Examiner
Art Unit 1624**

June 11, 2009